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Dorsey & Whitney LLP
Intellectual Property Department
Suite 1500
50 South Sixth Street
Minneapolis, MN 55402-1498

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,532,221

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,532,221, which claims the medical device Gynecare® Intergel, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 867 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 867 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of April 2, 2003 (68 Fed. Reg. 16061). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,453 - 474) + 985 \\ &= 1,475 \text{ days (4.0 years)}\end{aligned}$$

Since the regulatory review period began March 17, 1995, before the patent issued (July 2, 1996), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From March 17, 1995, to and including July 2, 1996, is 474 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,475 days, would extend the patent from July 2, 2013 to July 16, 2017, which is beyond the 14-year limit (the approval date is November 16, 2001, thus, the 14 year limit is November 16, 2015). The period of extension is thus limited to 867 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, July 2, 2013, to and including November 16, 2015, or 867 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,532,221

Granted: July 2, 1996

Original Expiration Date¹: July 2, 2013
Applicant: W. James Huang, et al.
Owner of Record: Lifecare Biomedical, Inc.
Title: Ionically Crosslinked Carboxyl-Containing Polysaccharides for Adhesion Prevention
Product Trade Name: Gynecare® Intergel
Term Extended: 867 days
Expiration Date of Extension: November 16, 2015

It is noted that a change of power of attorney and change in correspondence address were filed in the above captioned patent. Therefore, all correspondence regarding the patent term extension for U.S. Patent No. 5,532,221 is now being mailed to the address associated with customer number 25763.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450. By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

RE: Gynecare® Intergel
FDA Docket No.: 02E-0150

Attention: Beverly Friedman

¹Subject to the provisions of 35 U.S.C. § 41(b).